Chapter 4
Class A Pathogen Requirements

4.1 Introduction

This chapter principally discusses the Class A pathogen requirements in Subpart D of the 40 CFR Part 503 regulation. Biosolids that are sold or given away in a bag or other container for application to land **must** meet these requirements (see Section 3.4). Bulk biosolids applied to a lawn or home garden also **must** meet these requirements. Bulk biosolids applied to other types of land **must** meet these requirements if site restrictions are not met (see Chapter 5 for guidance on Class B biosolids). Some discussion is, however, presented of vector attraction reduction.

There are six alternative methods for demonstrating Class A pathogen reduction. Two of these alternatives provide continuity with 40 CFR Part 257 by allowing use of Processes to Further Reduce Pathogens (PFRPs) and equivalent technologies (see Sections 4.8 and 4.9). Any one of these six alternatives may be met for the sewage sludge to be Class A with respect to pathogens. The implicit objective of all these requirements is to reduce pathogen densities to below detectable limits which are:

Salmonella sp.	less than 3 MPN per 4 grams total solids biosolids (dry weight basis)
Enteric viruses[1]	less than 1 PFU per 4 grams total solids biosolids (dry weight basis)
Viable helminth ova	less than 1 viable helminth ova/ 4 gram total solids biosolids (dry weight basis)

One of the vector attraction reduction requirements (see Chapter 8) also must be met when biosolids are applied to the land or placed on a surface disposal site. To meet the Part 503 regulatory requirements, pathogen reduction must be met before vector attraction reduction or at the same time vector attraction reduction is achieved.

For the following sections, the title of each section provides the number of the Subpart D requirement discussed in the section. The exact regulatory language can be found in Appendix B, which is a reproduction of Subpart D. Chapters 9 and 10 provide guidance on the sampling and analysis needed to meet the Class A microbiological monitoring requirements.

[1] Enteric viruses are monitored using a method that detects several enterovirus species--a subset of enteric viruses. This method is presumed to be a good indicator of enteric viruses. Since the objective of the Part 503 regulation is to reduce all enteric viruses to less than 1 PFU per 4 grams total solids sewage sludge, this document refers to "enteric viruses" when discussing this requirement, although, in reality, the detection method enumerates only enteroviruses.

4.2 Vector Attraction Reduction to Occur With or After Class A Pathogen Reduction [503.32(a)(2)]

Although vector attraction reduction and pathogen reduction are separate requirements, they are often related steps of a process. Chapter 8 discusses the vector attraction reduction options in greater detail.

The order of Class A pathogen reduction in relation to the reduction of vector attraction is important when certain vector attraction reduction options are used. Part 503.32(a)(2) requires that Class A pathogen reduction be accomplished before or at the same time as vector attraction reduction, except for vector attraction reduction by alkali addition [503.33(b)(6)] or drying [503.33(b)(7) and (8)] (see Chapter 8).

This requirement is necessary to prevent the growth of bacterial pathogens after sewage sludge is treated. Contamination of biosolids with a bacterial pathogen after one of the Class A pathogen reduction alternatives has been conducted may allow extensive bacterial growth unless: a) an inhibitory chemical is present, b) the biosolids are too dry to allow bacterial growth, c) little food remains for the microorganisms to consume, or d) an abundant population of non-pathogenic bacteria is present. Vegetative cells of non-pathogenic bacteria repress the growth of pathogenic bacteria by "competitive inhibition" which is in substantial part due to competition for nutrients. It should be noted that vector attraction reduction by alkali addition [503.3(b)(6)] or drying [503.3(b)(7)] and (8) is based on the characteristic of the biosolids (pH or total solids) remaining elevated. Should the pH drop or the biosolids absorb moisture, the biosolids may be more hospitable to microorganisms, and pathogenic bacteria, if introduced, may grow. Therefore it is recommended that biosolids treated with these methods be stored appropriately.

Biological treatment processes like anaerobic digestion, aerobic digestion, and composting produce changes in the

sewage sludge so that it satisfies one of the vector attraction reduction requirements [503.3(b)(1) through (5)]. They repress bacterial growth by minimizing the food supply and providing competition for the remaining food from non-pathogenic organisms. The pathogen reduction alternative must precede the vector attraction reduction process; otherwise, the large number of non-pathogenic bacterial cells would be killed and growth of pathogenic bacteria could occur. Certain pathogen reduction processes such as composting accomplish vector attraction reduction by a biological process simultaneously with thermal reduction of pathogens. A non-pathogenic bacterial community survives which adequately suppresses growth of pathogenic bacteria.

In the case of Class B biosolids, a population of non-pathogenic bacteria is retained and inhibits the growth of pathogenic bacteria through competition, and site restrictions are imposed with their land application to reduce the risk of exposure to pathogens. Therefore, bacterial growth is not a concern for Class B biosolids, and vector attraction reduction and pathogen reduction for compliance with the Part 503 Rule requirements may be met in any order.

4.3 Monitoring of Fecal Coliform or *Salmonella* sp. to Detect Growth of Bacterial Pathogens [503.32(a)(3)-(8)]

The goal of Class A processes is to reduce the level of pathogens to below detectable levels and below the level at which they are infectious. The Class A processes have been shown to sufficiently reduce pathogen levels in biosolids, and studies to date have not found that the growth of pathogenic bacteria may occur in materials after processes take place or during storage. Favorable conditions for the growth of pathogenic bacteria would be: adequate moisture, absence of an inhibitory chemical, and inadequate reduction of nutritive value of the sewage sludges.

Because Class A biosolids may be used without site restrictions, all Class A material must be tested to show that the microbiological requirements are met at the time when *it is ready to be used or disposed.* In addition to meeting process requirements, Class A biosolids must meet one of the following requirements:

- Either the density of fecal coliforms in the sewage sludge be less than 1,000 MPN[2] per gram total solids (dry weight basis).
- Or the density of *Salmonella* sp. bacteria in the sewage be less than 3 MPN per 4 grams of total solids (dry weight basis).

Although the Part 503 regulation does not specify the number of samples that should be taken to show compliance with Class A density requirements, sampling programs should provide adequate representation of the biosolids generated. Chapter 9 provides guidance for calculating the number of samples that should be taken per sampling event. Unlike Class B biosolids, compliance with Class A requirements is not based on an average value. **Each sample analyzed must comply with the numerical requirements.**

The microbiological requirement must be met either:

- At the time of use or disposal[3], or
- At the time the biosolids are prepared for sale or give away in a bag or other container for land application, or
- At the time the biosolids or material derived from the biosolids is prepared to meet the requirements in 503.10(b), 503. 10(c), 503. 10(e), or 503. 10(f)[4].

If a facility stores material before it is distributed for use or disposal, microbiological testing should take place after storage.

In each case, the timing represents the last practical monitoring point before the biosolids are applied to the land or placed on a surface disposal site. Biosolids that are sold or given away cannot be monitored just prior to actual use or disposal; instead monitoring is required as it is prepared for sale or give away. Biosolids that meet the 503.10(b, c, d, or e) requirements are considered "Exceptional Quality" and are therefore not subject to further control (see Section 1.4). For this reason, the microbiological requirements must be met at the time the biosolids are prepared to meet the 503.10 requirements, which in most cases is the last time the biosolids are under the control of a biosolids preparer.

As discussed in Chapter 9, the timing of pathogen sampling is also a function of laboratory turnaround time. Obtaining results for fecal coliform and *Salmonella* sp. analysis may take several days if tests are performed in-house, but commercial labs may require more time to process and report results. It is not unusual for laboratories to have a turnaround time of 2 weeks, even for simple tests such as fecal coliform. If this is the case, this time should be factored into the sampling program so that results can be obtained before biosolids are distributed for use or disposal.

Monitoring Fecal Coliforms or Salmonella sp.

Fecal coliforms are used in the Part 503 as an indicator organism, meaning that they were selected to be monitored because reduction in fecal coliforms correlates to reduction in *Salmonella* sp. and other organisms. The re-

[2]The membrane filter method is not allowed for Class A because, at the low fecal coliform densities expected, the filter would have too high a loading of sewage sludge solids to permit a reliable count of the number of fecal coliform colonies.

[3]Minus the time needed to test the biosolids and obtain the test results prior to use or disposal (see Chapter 10).

[4]The 503.10(b)(c)(e) and (f) requirements are not discussed in this document.

quirements were based on experimental work by Yanko (1987) and correlations developed from Yanko's data by Farrell (1993) which show that this level of fecal coliforms correlate with a very low level of *Salmonella* sp. detection in composted sewage sludge (EPA, 1992).

Anecdotal reports suggest that some composting facilities may have difficulty meeting this requirement even when *Salmonella* sp. are not detected. This might be expected under several circumstances. For example, very severe thermal treatment of sewage sludge during composting can totally eliminate *Salmonella* sp. yet leave residual fecal coliforms. If the sewage sludge has been poorly composted and thus is a good food source, fecal coliforms may grow after the compost cools down from thermophilic temperatures. Because the *Salmonella* sp. are absent, they cannot grow. An even more probable circumstance could occur if the sewage sludge is treated with lime before composting. Lime effectively destroys *Salmonella* sp. in sewage sludge and leaves surviving fecal coliforms (Farrell et al., 1974). Under conditions favorable for growth, the fecal coliforms can regrow to levels higher than 1,000 MPN per gram. Research has shown that detection of *Salmonella* sp. is much rarer in composted sewage sludge that has been lime treated and composted than detection of fecal coliforms. *Fecal coliform densities maybe high therefore compared to pathogen densities in such cases and maybe overly conservative.* For this reason, all of the Part 503 Class A alternatives allow the direct measurement of *Salmonella* sp. or fecal coliform analysis, but do not require both.

4.4 Alternative 1: Thermally Treated Sewage Sludge [503.32(a)(3)]

This alternative may be used when the pathogen reduction process uses specific time-temperature regimes to reduce pathogens. Under these circumstances, time-consuming and expensive tests for the presence of specific pathogens can be avoided. It is only necessary to demonstrate that:

- Either fecal coliform densities are below 1,000 MPN per gram of total solids (dry weight basis), or *Salmonella* sp. bacteria are below detection limits (3 MPN per 4 grams total solids [dry weight basis]) at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or given away in a bag or other container for land application, **or** at the time the sewage sludge or material derived from the sewage sludge is prepared to meet the requirements in 503.10(b), 503.10(c), 503.10(e), or 503.10(f).

- And the required time-temperature regimes are met.

Time-Temperature Requirement

Four different time-temperature regimes are given in Alternative 1. Each regime is based on the percent solids of the sewage sludge and on operating parameters of the treatment process. Experimental evidence (EPA, 1992) demonstrates that these four time-temperature regimes reduce the pathogenic organisms to below detectable levels.

The four time-temperature regimes are summarized in Table 4-1. They involve two different time-temperature equations. The equation used in Regimes A through C results in requirements that are more stringent than the requirement obtained using the equation in Regime D. For any given time, the temperature calculated for the Regime D equation will be 3 Celsius degrees (5.4 Fahrenheit degrees) lower than the temperature calculated for the Regimes A through C equation.

The time-temperature relationships described for Alternative 1 are based on extensive research conducted to correlate the reduction of various pathogens in sewage sludge to varying degrees of thermal treatment. The resulting time-temperature relationship which is the basis for Alternative 1 is shown in Figure 4-1. These requirements are similar to the FDA requirements for treatment of eggnog, a food product with flow characteristics similar to those of liquid sewage sludge. The Regimes A through D differ depending on the characteristics of sewage sludge treated and the type of process used because of the varying efficiency of heat transfer under different conditions.

It is important to note that **it is mandatory for all sewage sludge particles to meet the time-temperature regime.** Therefore, testing of temperatures throughout the sewage sludge mass and agitating the material to ensure uniformity would be appropriate. For processes such as thermophilic digestion, it is important that the digester design not allow for short circuiting of untreated sewage sludge. One approach that has been used to overcome this problem has been to draw off treated sewage sludge and charge feed intermittently with a sufficient time period between draw-down and feeding to meet the time-temperature requirement of Alternative 1. Another option would be to carry out the process in two or more vessels in series so as to prevent bypassing.

These time-temperature regimes are not intended to be used for composting (the time-temperature regime for composting is covered in Alternative 5: Processes to Further Reduce Pathogens).

A more conservative equation is required for sewage sludges with 7% or more solids (i.e., those covered by Regimes A and B) because these sewage sludges form an internal structure that inhibits the mixing that contributes to uniform distribution of temperature. The more stringent equation is also used in Regime C (even though this regime applies to sewage sludges with less than 7% solids) because insufficient information is available to apply the less stringent equation for times less than 30 minutes.

The time-temperature requirements apply to every particle of sewage sludge processed. Time at the desired temperature is readily determined for batch or plug flow operations, or even laminar flow in pipes. Time of contact also can be calculated for a number of completely mixed

Table 4-1. The Four Time-Temperature Regimes for Alternative 1 (Thermally Treated Sewage Sludge) [503.32(a)(3)]

Regime	Part 503 Section	Applies to	Required Time-Temperature[1]
A	503.32(a)(3)(ii)(A)	Sewage sludge with at least 7% solids (except those covered by Regime B)	$D = 131{,}700{,}000/10^{0.1400t}$ $t \geq 50°C$ (122°F)[2] $D \geq 0.0139$ (i.e., 20 minutes)[3]
B	503.32(a)(3)(ii)(B)	Sewage sludge with at least 7% solids that are small particles heated by contact with either warmed gases or an immiscible liquid[4]	$D = 131{,}700{,}000/10^{0.1400t}$ $t \geq 50°C$ (122°F)[2] $D \geq 1.74 \times 10^{-4}$ (i.e., 15 seconds)[5]
C	503.32(a)(3)(ii)(C)	Sewage sludge with less than 7% solids treated in processes with less than 30 minutes contact time	$D = 131{,}700{,}000/10^{0.1400t}$ 1.74×10^{-4} (i.e., 15 seconds) $\leq D \leq 0.021$ (i.e. 30 minutes)[6]
D	503.32(a)(3)(ii)(D)	Sewage sludge with less than 7% solids treated in processes with at least 30 minutes contact time	$D = 50{,}070{,}000/10^{0.1400t}$ $t \geq 50°C$ (122°F)[2] $D \geq 0.021$ (i.e. 30 minutes)[7]

[1]D = time in days; t = temperature (°C).
[2]The restriction to temperatures of at least 50°C (122°F) is imposed because information on the time-temperature relationship at lower temperatures is uncertain.
[3]A minimum time at 20 minutes is required to ensure that the sewage sludge has been uniformly heated.
[4]Two examples of sewage sludge to which this requirement applies are:
- Sewage sludge cake that is mixed with previously dried solids to make the entire mass a mixture of separate particles, and is then dried by contact with a hot gas stream in a rotary drier.
- Sewage sludge dried in a multiple-effect evaporator system in which the system sludge particles are suspended in a hot oil that is heated by indirect heat transfer with condensing steam.

[5]Time-at-temperature of as little as 15 seconds is allowed because, for this type of sewage sludge, heat transfer between particles and the healing fluid is excellent. Note that the temperature is the temperature achieved by the sewage sludge particles, not the temperature of the carrier medium.
[6]Time-at-temperature of as little as 15 seconds is allowed because heat transfer and uniformity of temperature is excellent in thiswage sludge. The maximum time of 30 minutes is specified because a less stringent regime (D) applies when time-at-temperature is 30 minutes or more.
[7]Time-at-temperature of at least 30 minutes is required because information on the effectiveness of this time-temperature regime for reducing pathogens at temperatures of less than 30 minutes is uncertain.

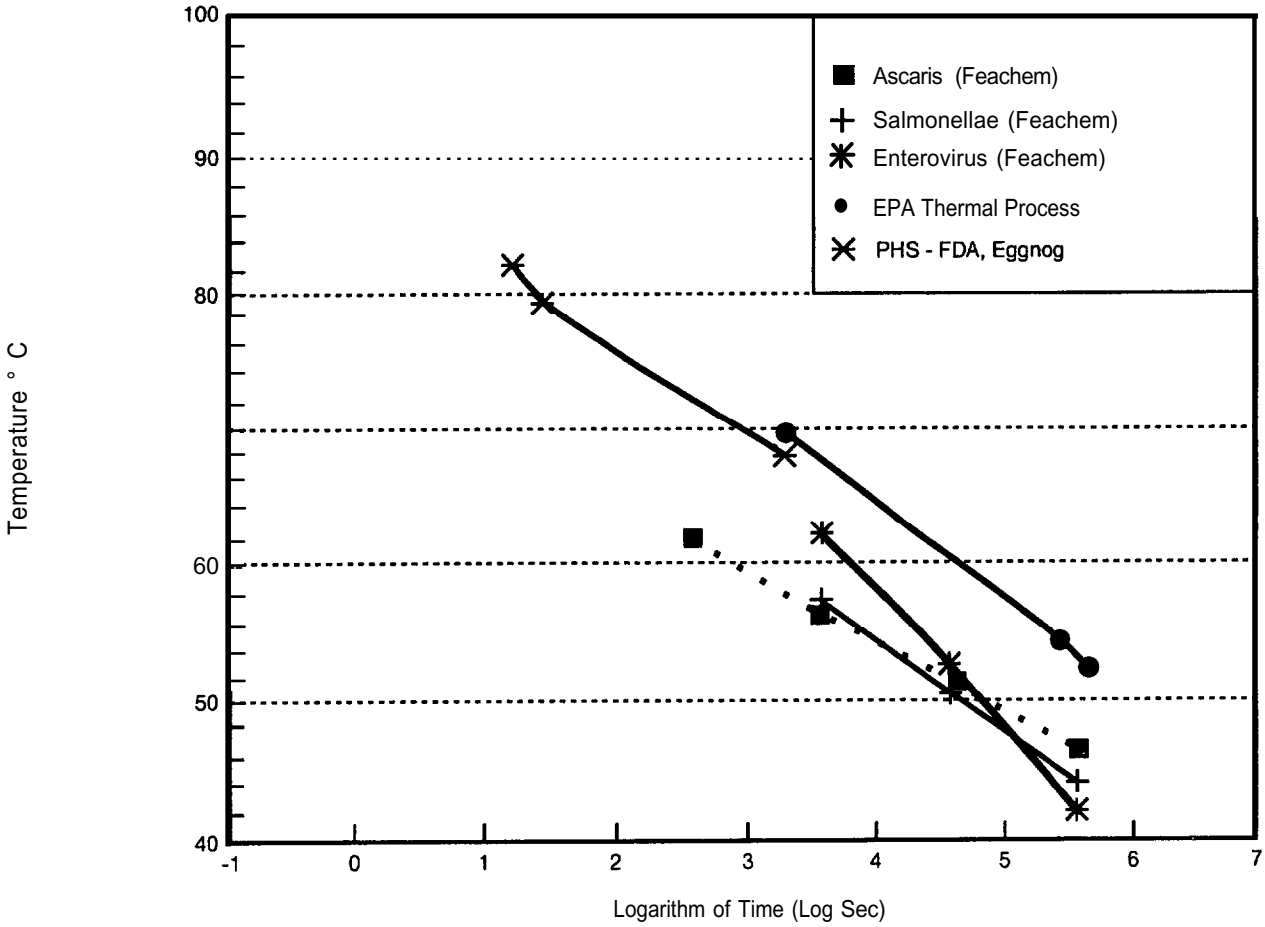

Figure 4-1. EPA's time-temperature relationship for thermal disinfection compared with other time-temperature relationships.

reactors in series (Schafer, et al, 1994). However, there are concerns that flow-through systems may permit some sludge to pass through without adequate treatment. It is recommended that facilities wishing to use this alternative for a flow-through system conduct tracer studies to demonstrate that sewage sludge is treated at the required temperature for sufficient time.

Vector Attraction Reduction

Thermally treated sewage sludge must be treated by an additional vector attraction reduction process since thermal treatment does not necessarily break down the volatile solids in sewage sludge. Vector attraction reduction can be met by further processing the sewage sludge with pH adjustment or heat drying (Options 6 and 7), or by meeting one of the other options (Options 8 – 11). Options 1 through 5 would not be applicable to thermally treated sludge unless the sludge was subject to biological digestion after or during thermal treatment.

Example of Meeting Class A Pathogen and Vector Attraction Reduction Requirements

Type of Facility	Thermophilic Anaerobic Digester Class A
	Digested sewage sludge is retained for at least 5 days at 50°C (Regime D). Sewage sludge is agitated regularly to ensure thorough mixing, and temperatures are monitored continually in a batch mode of operation.
Testing	Sewage sludge is sampled 6 times each year for pollutants and fecal coliforms. Compliance with vector attraction reduction is also monitored.
Vector Attraction Reduction	VAR is met by reducing volatile solids by over 38 percent. Five samples of input and output sewage sludge from each batch are analyzed for volatile solids content over a period of two weeks.
Use or Disposal	The Class A biosolids are land applied.

Microbiological Requirement

Microbiological monitoring for either fecal coliforms or *Salmonella* sp. is required to ensure that growth of bacterial pathogens has not occurred.

4.5 Alternative 2: Sewage Sludge Treated in a High pH-High Temperature Process (Alkaline Treatment) [503.32(a)(4)]

This alternative describes conditions of a high temperature-high pH process that has proven effective in reducing pathogens to below detectable levels. The process conditions required by the Part 503 regulation are:

- Elevating pH to greater than 12 and maintaining the pH for more than 72 hours.
- Maintaining the temperature above 52°C (126°F) throughout the sewage sludge for at least 12 hours during the period that the pH is greater than 12.
- Air drying to over 50% solids after the 72-hour period of elevated pH.

The hostile conditions of high pH, high temperature, and reduced moisture for prolonged time periods allow a variance to a less stringent time-temperature regime than for the thermal requirements under Alternative 1. The pH of the sewage sludge is measured at 25°C (77°F) or an appropriate correction is applied (see Section 10.7).

Example of Meeting Class A Pathogen and Vector Attraction Reduction

Type of Process Class	Alkaline Treatment
Pathogen Reduction	Alkaline material is used to bring sewage sludge pH to 12 for 72 hours during which time temperatures are above 52°C for 72 hours. Sewage sludge is agitated during the heat pulse phase to maintain even distribution, and temperature and pH are measured at multiple points within the sewage sludge. The sewage sludge is then moved to piles and maintained until moisture is reduced to 50 percent.
Testing	Piles are tested quarterly for pollutants and *Salmonella* sp. Samples are taken from stockpiled material, and material is not distributed for use or disposal until test results are received
Vector Attraction Reduction	VAR Option 6,pH adjustment; pH is to remain elevated until use/disposal.
Use or Disposal	During winter months (Nov-March), biosolids remain on site. In the spring, biosolids are retested for pathogens before being distributed.

Operational Issues

Because the elevated pH and temperature regimes must be met by the entire sewage sludge mass, operational protocols which include monitoring pH and temperature at various points in a batch and agitating the sewage sludge during operations to ensure consistent temperature and pH are appropriate.

Vector Attraction Reduction

The pH requirement of vector attraction reduction Option 6 is met when Alternative 2 is met. Compliance with Alternative 2 exceeds the pH requirements of Option 6.

Microbiological Requirements

As with all the Class A alternatives, microbiological monitoring for fecal coliforms or *Salmonella* sp. is required (see Section 4.3) to ensure that pathogens have been reduced and growth of pathogenic bacteria has not occurred.

4.6 Alternative 3: Sewage Sludge Treated in Other Processes [503.32(a)(5)]

This alternative applies to sewage sludge treated by processes that do not meet the process conditions required by Alternatives 1 and 2. This requirement relies on comprehensive monitoring of bacteria, enteric viruses and viable helminth ova to demonstrate adequate reduction of pathogens:

- Either the density of fecal coliforms in the sewage sludge must be less than 1000 MPN per gram of total solids (dry weight basis), or the *Salmonella* sp. bacteria in sewage sludge must be less than 3 MPN per 4 grams of total solids (dry weight basis) at the time the sewage is used or disposed, at the time the sewage sludge is prepared for sale or given away in a bag or other container for land application, or at the time the sewage sludge or material derived from the sewage sludge is prepared to meet the requirements in 503.10(b), 503.10(c), 503.10(e), or 503.10(f).
- The density of enteric viruses in the sewage sludge after pathogen treatment must be less than 1 PFU per 4 grams of total solids (dry weight basis).
- The density of viable helminth ova in the sewage sludge after pathogen treatment must be less than 1 per 4 grams of total solids (dry weight basis).

Testing for enteric viruses and viable helminth ova can be complicated by the fact that they are sometimes not present in the untreated sewage sludge. In this case, an absence of the organisms in the treated sewage sludge does not demonstrate that the process can reduce them to below detectable limits. For this reason, Alternative 3 requires that the feed sewage sludge be analyzed for enteric viruses and viable helminth ova. If these organisms are not detected in the feed sewage sludge, the sewage sludge is presumed to be acceptable as a Class A material until the next monitoring episode. Monitoring is continued until enteric viruses and/or viable helminth ova are detected in the feed sewage sludge (i.e., the density of enteric viruses is greater than or equal to 1 PFU per 4 grams total solids (dry weight basis) and/or the density of viable helminth ova is greater than or equal to 1 per 4 grams total solids (dry weight basis). At this point, the treated sewage sludge is analyzed to see if these organisms survived treatment. If enteric viruses densities are below detection limits, the sewage sludge meets Class A requirements for enteric viruses, and will continue to do so as long as the treatment process is operated under the same conditions that successfully reduced the enteric virus densities. If the viable helminth ova densities are below detection limits, the process meets the Class A requirements for enteric viruses and will continue to do so as long as the treatment process is operated under the same conditions that successfully reduced the viable helminth ova densities. Thus, it is essential to monitor and document operating conditions until adequate enteric virus and helminth ova reduction has been successfully demonstrated. Samples of untreated and treated sewage sludge must correspond (see Section 7.4).

Enteric Virus and Viable Helminth Ova Testing

Tests for enteric viruses and viable helminth ova take substantial time: 4 weeks to determine whether helminth ova are viable, and 2 weeks or longer for enteric viruses. The treatment works operator does not know whether the feed sewage sludge has enteric viruses or helminth ova until at least 2 to 4 weeks after the first samples for testing feed densities are taken. This works with rapid processes but long-term process systems need to have temporally related samples. In such cases, it may be feasible to obtain results within the processing time constraints. For enteric viruses, the sewage sludge should be stored frozen, unless the sample can be processed within 24 hours, in which case the samples may be stored at 4°C (39°F). For viable helminth ova, the sewage sludge should be stored at 4°C (39°F) (see Section 9.6).

Finding a laboratory that performs viable helminth ova and virus testing has been difficult for some sewage sludge preparers. Chapter 9 has more information on how to select a laboratory. State and Regional EPA sludge coordinators should also be contacted for information on qualified labs in the region.

Since this option relies on testing, rather than process and testing, to protect public health additional testings should be completed. At a minimum, a detailed sampling plan should be submitted to the permitting authority for review.

Vector Attraction Reduction

For both Alternatives 3 and 4, meeting vector attraction reduction depends on the process by which pathogen reduction is met. For example, sewage sludge subject to long-term storage may meet vector attraction reduction through volatile solids reduction (Options 1 – 3). Sewage sludges may also undergo additional processing or be applied following the requirements in Options 8 – 11.

Microbiological Requirements

As with all the Class A alternatives, microbiological monitoring for fecal coliforms or *Salmonella* sp. is required (see Section 4.3) to ensure that pathogens have been reduced and growth of pathogenic bacteria has not occurred.

4.7 Alternative 4: Sewage Sludge Treated in Unknown Processes [503.32(a)(6)]

The sewage sludge must meet the following limits at the time the biosolids (or material derived from sludge) are used or disposed, at the time the sewage sludge is prepared for sale or given away in a bag or other container for land application, or at the time the sewage sludge or material derived from the sewage sludge is prepared to meet the requirements in 503.10(b), 503.10(c), 503.10(e), or 503.10(f):

- The density of enteric viruses in the sewage sludge must be less than 1 PFU per 4 grams of total solids (dry weight basis).
- The density of viable helminth ova in the sewage sludge must be less than 1 per 4 grams of total solids (dry weight basis).

In addition, as for all Class A biosolids, the sewage sludge must meet fecal coliform or *Salmonella* sp. limits. As with Alternative 3, Alternative 4 depends on a successful sampling program that provides accurate representation of the sewage sludge's microbial quality (see Chapter 9).

Example Of Meeting Class A Pathogen Vector Attraction Reduction

Type of Facility	Unknown Process
Class	A
Pathogen Reduction	Sewage sludge is digested and retained in a lagoon up to 2 years. Sewage sludge is then moved to a stockpiling area where it may stay for up to 2 years.
Testing	Before sewage sludge is distributed, each pile, representing approximately 1 year of sewage sludge production, is tested for *Salmonella* sp., viable helminth ova, and enteric viruses. Since quarterly testing is mandated, based on the amount of sewage sludge which is used or disposed, four samples per pile are submitted
Vector Attraction Reduction	VAR is demonstrated by showing a 38 percent reduction in volatile solids. Records of incoming material and volume, bulk density, and percent volatile solids of outgoing material are used to calculate the reduction.
Distribution	Biosolids are distributed for land application and agricultural land.

Examples of situations where Alternative 4 may be used:

- Sewage sludge treatment process is unknown.
- The sewage sludge was produced with the process operating at conditions less stringent than the operating conditions at which the sewage sludge could qualify as Class A under other alternatives.

Enteric Virus and Viable Helminth Ova Testing

Tests for enteric viruses and viable helminth ova take substantial time: 4 weeks to determine whether helminth ova are viable, and 2 weeks or longer for enteric viruses. The treatment works operator does not know whether the feed sewage sludge has enteric viruses or helminth ova until at least 2 to 4 weeks after the first samples for testing feed densities are taken. This option works with rapid processes but long-term process systems need to have temporally related samples. In such cases, it may be feasible to obtain results within the processing time constraints. For enteric viruses, the sewage sludge should be stored frozen, unless the sample can be processed within 24 hours, in which case the samples may be stored at 4°C (39°F). For viable helminth ova, the sewage sludge should be stored at 4°C (39°F) (see Section 9.6).

Finding a laboratory that performs viable helminth ova and virus testing has been difficult for some sewage sludge preparers. Chapter 9 has more information on how to select a laboratory. State and Regional EPA sludge coordinators should also be contacted for information on qualified labs in the region.

Since this option relies on testing, rather than process and testing, to protect public health additional testings should be completed. At a minimum, a detailed sampling plan should be submitted to the permitting authority for review.

Vector Attraction Reduction

For both Alternatives 3 and 4, meeting vector attraction reduction depends on the process by which pathogen reduction is met. For example, sewage sludge subject to long-term storage may meet vector attraction reduction through volatile solids reduction (Options 1-3). Sewage sludges may also undergo additional processing or be applied following the requirement in Options 8-11.

4.8 Alternative 5: Use of PFRP [503.32(a)(7)]

Alternative 5 provides continuity with the 40 CFR Part 257 regulation. This alternative states that sewage sludge is considered to be Class A if:

- It has been treated in one of the Processes to Further Reduce Pathogens (PFRPs) listed in Appendix B of the regulation, and
- Either the density of fecal coliforms in the sewage sludge is less than 1,000 MPN per gram total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in the sewage sludge is less than 3 MPN per 4 grams total solids (dry weight basis) at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for land application, or at the

time the sewage sludge or material derived from the sewage sludge is prepared to meet the requirements in 503.10(b), 503.10(c), 503.10(e), or 503.10(f).

To meet this requirement, the sewage sludge treatment processes must be operated according to the conditions listed in Appendix B of the regulation.

The Appendix B list of PFRPs is reproduced in Table 4-2. This list is very similar to the PFRP technologies listed in 40 CFR Part 257, with two major differences:

- All requirements related to vector attraction reduction have been removed.
- All the "add-on" processes listed in Part 257 are now full-fledged PFRPs.

Under this Alternative, treatment processes classified as PFRP under 40 CFR Part 257 can continue to be operated; however, microbiological monitoring must now be performed to ensure that the pathogen density levels are below detection limits and to ensure that growth of *Salmonella* sp. bacteria does not occur between treatment and use or disposal.

For all PFRP processes, the goal of temperature monitoring should be to represent all areas of a batch or pile and to ensure that temperature profiles from multiple points in the process all meet mandated temperatures. In some instances it may be possible to monitor representative areas of a batch or pile or a reasonable worst case area to ensure compliance. Chapter 7 contains more guidelines about the operation of PFRP processes.

4.9 Alternative 6: Use of a Process Equivalent to PFRP [503.32(a)(8)]

The 40 CFR Part 257 regulation allowed any treatment process to be determined *equivalent* to a PFRP. Under Alternative 6, sewage sludge is considered to be a Class A sewage sludge if:

- It is treated by any process equivalent to a PFRP, **and**
- Either the density of fecal coliforms in the sewage sludge is less than 1,000 MPN per gram total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in the sewage sludge is less than 3 MPN per 4 grams total solids (dry weight basis) at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for land application, or at the time the sewage sludge or material derived from the sewage sludge is prepared to meet the requirements in 503.10(b), 503.10(c), 503.10(e), or 503.10(f).

Facilities that meet Alternative 6 for pathogen reduction must still meet vector attraction reduction requirements.

Processes Already Recommended as Equivalent

Processes recommended to be equivalent to PFRP are shown in Table 11.2. Products of all equivalent processes must still meet the Class A fecal coliform or *Salmonella* sp. requirements.

Who Determines Equivalency?

Part 503 gives the permitting authority responsibility for determining equivalency under Alternative 6. The EPA's Pathogen Equivalency Committee (PEC) is available as a resource to provide guidance and recommendations on equivalency determinations to both the permitting authority and the regulated community (see Chapter 11).

4.10 Frequency of Testing

The Part 503 regulation sets forth minimum sampling and monitoring requirements. Table 3-4 in Chapter 3 de-

Table 4-2. Processes to Further Reduce Pathogens (PFRPs) Listed in Appendix B of 40 CFR Part 503[1]

Composting	Using either the within-vessel composting method or the static aerated pile composting method, the temperature of sewage sludge is maintained at 55°C (131°F) or higher for 3 consecutive days. Using the windrow composting method, the temperature of the sewage sludge is maintained at 55°C (131°F) or higher for 15 consecutive days or longer. During the period when the compost is maintained at 55°C (131°F) or higher, there shall be a minimum of five turnings of the windrow.
Heat Drying	Sewage sludge is dried by direct or indirect contact with hot gases to reduce the moisture content of the sewage sludge to 10% or lower. Either the temperature of the sewage sludge particles exceeds 80°C (176°F) or the wet bulb temperature of the gas in contact with the sewage sludge as the sewage sludge leaves the dryer exceeds 80°C (176°F).
Heat Treatment	Liquid sewage sludge is heated to a temperature of 180°C (356°F) or higher for 30 minutes.
Thermophilic Aerobic Digestion	Liquid sewage sludge is agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time (i.e., the solids retention time) of the sewage sludge is 10 days at 55°C (131°F) to 60°C (140°F).
Beta Ray Irradiation	Sewage sludge is irradiated with beta rays from an electron accelerator at dosages of at least 1.0 megarad at room temperature (ca. 20°C [68°F]).
Gamma Ray Irradiation	Sewage sludge is irradiated with gamma rays from certain isotopes, such as Cobalt 60 and Cesium 137, at dosages of at least 1.0 megarad at room temperature (ca. 20°C [68°F]).
Pasteurization	The temperature of the sewage sludge is maintained at 70°C (158°F) or higher for 30 minutes or longer.

[1]Chapter 7 provides a detailed description of these technologies.

scribes the minimum frequency at which the sewage sludge must be sampled and analyzed for pathogens or vector attraction reduction in order to meet regulatory requirements. In addition to meeting these minimal requirements, the EPA recommends that sewage sludge generators and preparers also consider the potential public health impact pathways and possible liability issues when designing a sampling program. In some cases, it may be appropriate to sample more frequently than the required minimum.

Classification of biosolids as Class A or Class B is based on the most recent test results available. For example, if a facility produces a Class A compost, and sampling is performed once each quarter, the compost produced after each test result verifying Class A is returned is also assumed to be Class A, assuming that the same process continues to be followed. If a test result indicates that compost is not achieving Class A, all compost subsequently generated would be classified as Class B (assuming it meets Class B requirements). The Class B classification would remain until a test result confirming Class A quality is returned.

This raises several issues. Land application of Class B biosolids without site restrictions is a violation of the 503 regulation. In addition, if material is mistakenly classified as EQ biosolids and land applied without restriction to the public, the biosolids preparer may be inadvertently creating a public health risk as well as opening the facility to liability. The key issues to consider are:

At what point between the two sampling events does the material change from Class A to Class B? This depends on the particular situation. The Class B test result may be an exception – the result of cross contamination or faulty sampling or monitoring for one pile. On the other hand, the test result could be indicative of an operation which is not adequately reducing pathogens. The piles which were actually sampled may have been used or distributed under the classification of the previous lab results while lab results were pending (it generally takes 2 weeks to get lab results back). Because distribution of this material as Class A would constitute a violation of the Part 503 regulation, it is recommended that material generated during and subsequent to a sampling event remain on site until lab results are available.

What can you do if you suspect Class B biosolids have been distributed as Class A biosolids? The first question to answer is: has this material created a public health risk. The material should be resampled to determine if it is indeed Class B and not Class A. The Part 503 requires that Class A biosolids meet either the fecal coliform or the *Salmonella* sp. requirements (except for Alternatives 3 and 4). If the material is out of compliance for fecal coliforms, it should immediately be tested for *Salmonella* sp. (and vice versa). In addition, the validity of the test results should be checked by contacting the lab and reviewing the data.

Material distribution should then be tracked to determine where material has been used. Businesses and individuals to whom material has been distributed should be notified and informed of the potential quality issue. If material is stockpiled at distribution points such as at a soil blender or landscaper, the material should be retested for pathogen levels, and distribution be curtailed until the process is reviewed and acceptable results are achieved. The facility may even consider recalling the biosolids from the users.

If material has already been distributed to public access areas, including homes, gardens, parks, or other public areas, the biosolids preparer may consider testing the soil. If the testing indicates problems, corrective actions may be necessary.

How can a situation like this be avoided? There are several sampling practices that a facility should follow in order to avoid a situation like this.

First, sampling should take place close enough to the time of distribution so that results accurately reflect material quality.

If possible, material sampled and subsequently produced material should not be distributed until the results are available; there is usually a 2-week waiting period for lab results for fecal coliform or *Salmonella* sp. analysis.

More frequent sampling can help pinpoint when operational conditions change. This may allow more rapid correction of operations.

Stockpile biosolids in discrete batches and take multiple samples per sampling event. This will allow better identification of which piles may be out of compliance and will allow for the distribution of material that is identified as Class A.

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